

### **REMARKS**

By the amendments presented, the specification has been amended to correct a typographical error at page 9, line 28, in recitation of the term "tow" rather than the term "two".

Also by the amendments presented, the specification has been amended at page 12 to insert the title "Brief Description of the Drawings" before the disclosure describing Applicant's drawings.

Also by the amendments presented, Claims 3, 13, and 18 have been amended to more correctly recite the claimed limitations of the voltage range recited in Claim 3 and the fluid dose volume ranges recited in Claims 13 and 18.

Also by the amendments presented, Claim 16 has been amended to provide antecedent basis for recited claim terms.

Also by the amendments presented, Claim 20 has been amended to more clearly recite a method of using the electrostatic spray device described in Claim 2.

Upon entry of the amendments presented Claims 1-3, and 11-20 remain in the application. No additional claims fee is due.

### **Invention Synopsis**

The present invention is directed to a spray device such as an electrostatic spray device which is adapted to provide one or more unit doses of a fluid that can be used to treat maladies affecting the nasal region. The spray device of the present invention comprises a spray generator, a fluid reservoir, and a nosepiece, wherein the fluid reservoir comprises pharmaceutically acceptable nasal treatment agents such as medicaments, flavours, salts, and surfactants.

Fluid spray devices are conveniently used to treat symptoms associated with the nasal region and eyes, and are typically used to apply repetitive amounts of low doses of fluid for symptom relief. Typical fluid spray devices, however, can be difficult to use in that the fluid spray devices are generally designed for partial insertion into the nostrils for effective use. Use of typical fluid spray devices can also require uncomfortable positions for the user, such as a requirement to tilt one's head backwards to avoid the fluid from running out of the nose once dispensed. Unlike typical spray devices, the spray device of the present invention is capable of delivering fluid to the nasal cavity without the need to insert the spray device into the nostrils in addition to projecting fluid into the nose in the form of a ligament for a more effective delivery of nasal treatment agents.

### **Formal Matters**

#### **a) Drawings**

Applicant's drawings have been objected to under 37 CFR 1.83(a) for an alleged failure to show every feature of Applicant's invention as specified in the claims, wherein according to the Examiner these features include the spray generator, electrostatic spray with a voltage source, cone angle of varying size as in claims 11 and 12, a depiction of the spray device without substantially penetrating the nostrils, and the device spraying into two nostrils.

Applicant submits that features of Applicant's invention as specified in the claims are supported by Applicant's drawings. For example, in the specification at page 12, lines 26-28, the spray generator feature is described as a syringe pump (drawing element 7) which is used to generate the ligament of the spray (i.e., a spray generator). The electrostatic spray is described as drawing element 4, and in the specification at page 12, lines 28-31, the descriptions of the drawings are recited such that drawing element 9, the insulating casing of the spray device, encloses an electronic circuitry for supplying a high voltage. The cone angle as specified in Claims 11 and 12 is depicted in drawing Figure 4, wherein the spray cone is clearly labeled in the drawing as element 12 and described in the specification at page 13, lines 1-5, as having a cone angle  $\theta$  that can be measured to determine angles from about 20 to about 50°. The feature of the spray device without substantially penetrating the nostrils is shown in drawing Figures 1 and 2, wherein support is found in the specification at page 12, lines 18-26, for showing drawing element 2 (the turbinates) and drawing element 3 (the nostrils) of Figure 1 such that a method of administering a fluid to the nasal cavity involves effectively spraying into the nostrils to reach the turbinates without inserting an elastomeric nosepiece (drawing element 5 of Figure 2) of the spray device into the nostrils. Furthermore, in the specification at page 12, lines 18-23, description of drawing Figure 1 is provided for support of claiming that the device sprays simultaneously into two nostrils (drawing element 3 of Figure 1 depicts two nostrils).

In view of the foregoing remarks, Applicant submits that the drawings clearly show every feature of Applicant's invention as specified in the claims. Accordingly, the objection of the drawings under 37 CFR 1.83(a) is improper and should be withdrawn.

**b) Specification**

The Examiner has objected to the specification for a typographical error at page 9, line 28, in Applicant's recitation of the term "tow" rather than the term "two". Responsive to this objection, the specification has been amended to correct the typographical error, thus obviating this objection.

The Examiner has also indicated that Applicant should amend the specification to recite a drawings title before the disclosed section providing a description of the drawings. Applicant has amended the specification as suggested by the Examiner to recite at page 12, line 7, the title "Brief Description of the Drawings". Applicant submits that this amendment to the specification obviates the alleged drawings title informality.

**c) Rejections under 35 U.S.C. 112 (2nd paragraph)**

Claims 3 and 16-20 have been rejected under 35 U.S.C. 112 (2nd paragraph) as being indefinite for an alleged failure to provide antecedent basis for terms recited in Claims 3, 13, 14, 16, 18, and 19, and for improper claim dependency recited in Claim 20.

With regards to the 35 U.S.C. 112 (2nd paragraph) rejection of Claims 3, 13, 14, 18, and 19, Applicant has amended Claims 3, 13, and 18 to initially recite the claim limitations using the

indefinite article "a" rather than the definite article "the". Applicant submits that Claim 13 as amended provides antecedent basis for the fluid dose volume range as recited in its dependent Claim 14, as well as Claim 18 providing antecedent basis for this claimed limitation as recited in Claim 19 which depends from Claim 18. The amendment to Claims 3, 13 and 18 thus obviates this rejection as it would apply to Claims 3, 13, 14, 18, and 19.

With regards to the 35 U.S.C. 112 (2nd paragraph) rejection of Claim 16, Applicant submits that proper antecedent basis for recitation of "the fluid" in line 2 of this claim is provided in line 1 which recites "A method of administering a fluid". Applicant further submits that Claim 16 has been amended in line 1 to recite "a nasal cavity", thus providing antecedent basis for recitation of "the nasal cavity" in line 2. Furthermore, Claim 16 has been amended to recite the term "nostrils" rather than the phrase "the nostrils", and Applicant submits that initially recited plural terms are not preceded by articles because there are no plural indefinite article. Accordingly, the amendments to Claim 16 obviate this 35 U.S.C. 112 (2nd paragraph) rejection.

With regards to the 35 U.S.C. 112 (2nd paragraph) rejection of Claim 20, Applicant submits that Claim 20 has been amended to more clearly recite the method of using the electrostatic spray device described in Claim 2, thus obviating this rejection as it would apply to amended Claim 20.

In light of the amendments to Claims 3, 13, 16, 18, and 20, and in light of the foregoing observations, Applicants submits that Claims 3, 13, 14, 16, 18, 19, and 20 as they now stand are in complete compliance with the definiteness requirement of 35 U.S.C. 112 (2nd paragraph). These rejections should, therefore, be withdrawn.

#### Art Rejection

Claims 1-3 and 11-19 have been rejected as being unpatentably obvious over Jeffries et al. (U.S. Patent 5,490,633) in view of Coffee (U.S. Patent 6,105,571). The Examiner contends that it would have been obvious to incorporate the nosepiece as disclosed by Jeffries onto a spray device as disclosed by Coffee, to thereby realize Applicant's invention. Applicant respectfully traverses this rejection.

Jeffries et al. disclose an apparatus for the electrostatic spraying of fluids in the form of a ligament wherein the fluid ligament has a dimension substantially smaller than the dimension of an orifice of the spray device, and a diameter that is no greater than 50% of the diameter of the orifice. The fluids disclosed in the Jeffries et al. reference are particularly aqueous, alcohol, and aqueous/alcohol based liquids that are commonly used in personal care products such as deodorants, anti-perspirants, scents, and hair sprays. Jeffries et al. further disclose that typically a high voltage, a voltage typically of the order of 10 to 25 kV, is applied to the fluids to be sprayed from the electrostatic spray device. Jeffries et al., however, fail to disclose a spray device such as an electrostatic spray device that 1) comprises a fluid reservoir containing a pharmaceutically acceptable fluid, or 2) is adapted to produce a spray having a fluid ligament wherein the ligament has a length of from 1 to 20 mm from a nosepiece end to a delivery end.

Coffee discloses an electrohydrodynamic (i.e., electrostatic) dispensing device for comminuting a liquid suitable for use in agriculture, the automotive industry, cosmetics, and medicines, wherein the medicines include medicaments for pharmaceutical health care use or medically useful compounds such as anesthetics. A preferred liquid is a liquid medicament suitable for inhaled administration which includes those medicaments used for the treatment of disorders of the respiratory tract including administration to the nasal mucosa. According to the Coffee reference, the liquid is communicated by an induced electrical charge of the order of 1-20 kilovolts, for example 10 kilovolts, and the liquid emerges from the dispensing device as a fast jet that breaks into charged droplets that can be used for inhalation therapy. Coffee, however, fails to disclose a dispensing device such as an electrostatic spray device which is adapted to produce a spray having a fluid ligament wherein the ligament has a length of from 1 to 20 mm from a nosepiece end to a delivery end.

Applicant submits that the combined disclosure of the Jeffries et al. and Coffee references would not obviously lead the skilled artisan to a realization of Applicant's invention as it relates to Claims 1-3 and 11-19. First, the Jeffries et al. reference fails to teach or suggest a spray device for dispensing a pharmaceutically acceptable fluid, this particularly applied reference teaches and suggests spray devices such as electrostatic spray devices which can dispense liquids that are commonly used in personal care products such as deodorants, anti-perspirants, scents, and hair sprays. Secondly, despite Coffee teaching of spray devices which dispense a pharmaceutically acceptable fluid such as a medicament, Coffee fails to teach and suggest a spray device that is adapted to produce a spray having a specifically defined fluid ligament. By contrast, Applicant's Claims 1-3 and 11-19 are limited to a packaged spray device comprising a fluid reservoir containing a pharmaceutically acceptable fluid in combination with the device being adapted to produce a spray having a specifically defined fluid ligament.

The Examiner contends that it would have been obvious to incorporate the fluid ligament nosepiece of Jeffries et al. onto a spray device of Coffee to thereby realize Applicant's invention of Claims 1-3 and 11-19. Applicant respectfully disagrees. Applicant submits that Jeffries et al. fail to recognize that spray devices adapted to produce a spray having a fluid ligament can comprise a fluid reservoir containing a pharmaceutically acceptable fluid and, therefore, provides no motivation to combine their teaching with a reference that teaches and suggests an element of Applicant's spray device that is directed to the fluid reservoir containing a pharmaceutically acceptable fluid. Although Coffee teaches spray devices such as electrostatic spray devices which can dispense a pharmaceutically acceptable fluid such as a medicament, Coffee fails to suggest such a device that is adapted to produce a spray having a specifically defined fluid ligament. Therefore, Applicant submits that Jeffries et al. provide no motivation to combine their teaching with Coffee, nor does Coffee provide motivation to combine his teaching with Jeffries et al.

Moreover, a spray device manufactured by combining the teachings of Jeffries et al. and Coffee would still be deficient in containing a fluid ligament that has a length of from 1 to 20 mm


from a nosepiece end to a delivery end. The Examiner contends that the ligament length feature of Applicant's spray device is within routine discovery of the skilled artisan. If this ligament length feature involves only routine skill, why didn't Jeffries et al. teach or suggest this feature? Jeffries et al. provide detailed description of its ligament including the fluid ligament having a dimension substantially smaller than the dimension of an orifice of the spray device, and a diameter that is no greater than 50% of the diameter of the orifice, but fail to mention altogether any length features of the ligament. Applicant submits that the combined disclosure of the Jeffries et al. and Coffee references fails to teach or suggest Applicant's spray device that comprises a fluid reservoir containing a pharmaceutically acceptable fluid and that is adapted to produce a spray having a specifically defined fluid ligament, wherein the ligament has a length of from 1 to 20 mm from a nosepiece end to a delivery end.

In view of the foregoing remarks, it is respectfully submitted that this combination of applied references fails to teach or suggest Applicant's claimed spray device. Accordingly, rejection of Applicant's Claims 1-3 and 11-19 as unpatentably obvious over Jeffries et al. in view of Coffee is improper and should be withdrawn.

#### Conclusions

Applicant has made an earnest effort to place his application in proper form and to distinguish the claimed invention from the applied prior art. WHEREFORE, reconsideration of this application, withdrawal of the rejections under 35 U.S.C. 112 (2nd paragraph) and 35 U.S.C. 103, and allowance of Claims 1-3 and 11-20 are respectfully requested.

Respectfully submitted,  
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**Version with Markings to Show Changes Made****In The Specification:**

At page 9, the paragraph at lines 21-36 has been amended as follows:

--In order to provide clean cut-off at low unit volumes the device preferably comprises an elastomeric, self-sealing exit valve having a fluid side and a delivery side, the valve opening to allow passage of the fluid when pressure is applied to fluid on the fluid side and sealing when the pressure is removed. By "exit valve" is meant that the elastomeric valve is the final dispensing valve and that there are no other elements of the device which mechanically, restrict or modify the flow of the fluid on the downstream side of the valve. In highly preferred embodiments herein the valve is a slit valve. The valve can comprise a single slit or [two] two or more intersecting slits, to form a cross shape for example. Preferably, however, the valve comprises a single slit. Although the valve can be flat it is preferably dome-shaped by which is meant that a non-planar valve having a recess such as with a hemispherical or frustoconical dome. In preferred embodiments the valve is essentially in the form of a hemispherical dome having a flange along its perimeter so that a collar can be fitted to retain the valve in the device. The diameter of the valve, including the flange, is typically from about 2 to about 6 mm with the dome portion having a diameter of from about 1 to about 4 mm, typically about 2.5mm and a thickness from inside to--

At page 12, line 7, the following title has been inserted:

--Brief Description of the Drawings--

**In The Claims:**

Claims 3, 13, 16, 18, and 20 have been amended as follows:

Claim 3. (Amended) An electrostatic spray device according to Claim 2 wherein a voltage [in the] having a range from about 1 kV up to 10 kV is applied to the fluid.

Claim 13. (Amended) A spray device according to Claim 1 wherein the device is adapted to provide a unit fluid dose with a volume [in the] having a range from about 1 to about 20  $\mu$ l.

Claim 16. (Amended) A method of administering a fluid to [the] a nasal cavity from a spray device, the method comprising spraying the fluid into the nasal cavity without substantial penetration of the device into [the] nostrils.

Claim 18. (Amended) A method according to Claim 16 wherein the device is adapted to provide a unit fluid dose with a volume[in the] having a range from about 1 to about 20  $\mu$ l.

Claim 20. (Amended) A method according to Claim 16 using [a] the electrostatic spray device [according to] described in Claim 2.